

MDHHS Recommendations for CON Standards Scheduled for 2022 Review

Air Ambulance Services Standards

Department Recommendations: Air Ambulance services should continue to be regulated until the Department's Emergency Medical Services (EMS) Licensing can update its rules to include Air Ambulance specific requirements.

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the Air Ambulance Services Standards are scheduled for review in calendar year 2022.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 8 - 22, 2021. Testimony was received from four organizations and is summarized as follows:

1. *Kathy Donovan, Children's Hospital of Michigan*
 - Children's Hospital of Michigan supports the continued regulation of Air Ambulance Services and recommends no changes at this time.
2. *Tiffany Obetts, Spectrum Health*
 - Spectrum Health supports the continued regulation of Air Ambulance Services "until the updated EMS Life Support Agencies and Medical Control rules are in place. This rule set incorporates current CON quality provisions that will ensure air ambulance providers are operating with clear standards."
3. *Rob Casalou, Saint Joseph Mercy Health System and Mercy Health*
 - Supports the continued regulation of Air Ambulance Services and recommends no changes at this time.
4. *Patrick O'Donovan, Beaumont Health*
 - Supports the continued regulation of Air Ambulance Services and recommends no changes at this time.

Background:

The Federal Aviation Administration Authorization (FAA) Act of 1994 preempts need determination requirements of state programs for AA services (additional information below). As such, the Michigan CON program may not include language that restricts AA service in Michigan based on need for the service. The Department has historically recommended CON deregulation of AA service due to this federal restriction of regulating need. However, many individuals and organizations involved in AA services in Michigan have advocated to continue CON regulation of this service to preserve the quality-related requirements that are not

federally restricted.

In 2013, the CON Commission held an AA workgroup that focused on updating the Michigan CON AA Services Standard to be aligned with the federal law. At its March 18, 2014 meeting, the Commission took final action on standards that removed all language regarding need. At this meeting, the Commission stated that AA Service would remain regulated by CON until the EMS licensing in the Department of Health and Human Services could update the licensure process to include AA specific criteria that are currently found in the CON standards. In 2016 and 2019, this was reaffirmed by the Commission as administrative rules had not been finalized.

Currently, the Michigan administrative rules for EMS are pending in the rulemaking process to update language regarding Air Ambulances. The Department will keep the Commission updated on the progress of these rules through the rulemaking process.

Air Ambulances Services Survey Data for 2020:

Annual survey data for 2020 is the latest available and can be found here:

Air Ambulance Utilization

[https://www.michigan.gov/documents/mdhhs/Report_150 - Air Ambulance Utilization 2-21-18_614490_7.pdf](https://www.michigan.gov/documents/mdhhs/Report_150_-_Air_Ambulance_Utilization_2-21-18_614490_7.pdf)

Air Ambulance – Additional Services

[https://www.michigan.gov/documents/mdhhs/Report_152 - Air Ambulance Additional Services 2-21-18_614493_7.pdf](https://www.michigan.gov/documents/mdhhs/Report_152_-_Air_Ambulance_Additional_Services_2-21-18_614493_7.pdf)

MDHHS Recommendations for CON Standards Scheduled for 2022 Review

Computed Tomography (CT) Services Standards			
Department Recommendations: CT Scanner services should continue to be regulated by CON.			
Identified Issues	Issue Recommended for Substantive Review?	Recommended Course of Action to Review Issues	Other/Comments
UMHS recommends that the Commission determine if CT Scanners can be moved between multiple licensed facilities under common ownership. Regulate similarly to medical/surgical beds to improve provider flexibility to move services where needed to improve access.	No.		There is no indication that this is a widespread problem. There are provisions in the current standards to replace and relocate CT units by submitting an application.
UMHS recommends that pediatric patients are redefined as 0-21 (< 22 years of age) to more accurately classify pediatric patients.	No.		There is no indication that this is a widespread problem. Changing the definition of child/adolescent would have implications for other CON standards. Current CON standards do not prohibit patients aged 18-21 from receiving treatment on a dedicated pediatric CT unit as long as 70 percent of the procedures on the dedicated unit are done on patients less than 18 years of age. Further, this was recently reviewed by a CT workgroup in 2019, and no change was recommended to the standards as with or without a change there is no impact to patient care, access, or costs.

UMHS recommends modernization of process to replace a CT Scanner. “Applicants meeting “to be” established criteria would have the ability to file a Letter of Intent CoN waiver request and receive approval to replace a CT scanner without filing a CoN application.”	No.		There is no indication that this is a widespread problem. Changing the CON process for replacement of a CT Scanner would have implications for other CON standards related to replacement of services or equipment. Currently, replacement is a non-substantive review.
In Section 2(1)(j), for “CT Equivalents”, add the abbreviation “CTE” for easier read.	Yes.	The Department can draft language for the workgroup or Commission to consider.	This issue was identified by the Department. This is a technical edit.
In Section 2(1)(k), for what is NOT a CT scanner, either remove or explain “dental” so that ALL CT scanners that generate a peak power of 5kws or less are not considered CT scanners.	Yes.	The Department can draft language for the workgroup or Commission to consider.	This issue was identified by the Department. Receiving many questions from the Radiation Safety Section that chiropractors are requesting to register cone beam scanners in offices. Under the current definition, chiropractic cone beam scanners may need CON review and approval. Deregulation of cone beam CT was discussed in 2016 with the Commission voting to deregulate <i>dental</i> cone beam CT specifically.
In Section 5, replacement – Add language for lease renewal in CT Standards (similar to MRI Standards).	Yes.	The Department can draft language for the workgroup or Commission to consider.	This issue was identified by the Department.
In Section 17, add language to prohibit withdrawal of CT physician commitments during the review process. (See similar language in Section 18 of MRI standards)	Yes.	The Department can draft language for the workgroup or Commission to consider.	This issue was identified by the Department.

Other technical edits by the Department if needed.			None identified.
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Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the CT Services Standards are scheduled for review in calendar year 2022.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 8 - 22, 2021. Testimony was received from five organizations and is summarized as follows:

1. *Rob Casalou, Saint Joseph Mercy and Mercy Health System*
 - Supports continued regulation of CT Services and recommends no changes at this time.
2. *Patrick O'Donovan, Beaumont Health*
 - Supports continued regulation of CT Services and recommends no changes at this time.
3. *Cheryl Martin, Henry Ford Health System (HFHS)*
 - Supports continued regulation of CT Services and recommends no changes at this time.
4. *John C. Shull, Spectrum Health*
 - Supports continued regulation of CT Services and recommends no changes at this time.
5. *T. Anthony Denton, JD, MHA, Vikas Gulani, MD, Peter J. Strouse, MD, FACR, Chris J. Dickinson, MD, University of Michigan Health System*
 - Supports continued regulation of CT Services. Recommends review of three separate items:
 - System View – "Regulations currently exist for the movement of licensed medical/surgical beds between multiple licensed facilities under common ownership. Similar regulations which aggregate "system activity" to determine incremental qualification for other CoN Covered Services would significantly improve provider flexibility to place services where needed to improve access to healthcare."
 - Pediatric Age Definition – Redefine pediatric patients as 0-21 (< 22 years of age) to more accurately classify pediatric patients. "This proposed change would ensure that pediatric patients can obtain imaging with CT proximate within their health care environment, facilitating timely, efficient, and high-quality health care in patients 18-21 years old."
 - CT Scanner Replacement – Modernization of process to replace a CT Scanner. "Applicants meeting "to be" established criteria would have the ability to file a Letter of Intent CoN waiver request and receive approval to

replace a CT scanner without filing a CoN application. The described modernization would benefit both the applicant and the Department as resources could then be more effectively utilized. At the same time Department staff would still have ability to monitor cost and have a record of the replaced equipment.”

Background:

The CT Standards were reviewed with a workgroup in 2019. The current effective date of the CT Standards is November 9, 2020.

CT Survey Data for 2020

Annual survey data for 2020 is the latest available and can be found here:

Hospital and Freestanding CT

https://www.michigan.gov/documents/mdch/Report_101_506622_7.pdf

Portable and Ded Ped https://www.michigan.gov/documents/mdch/Report_102_506623_7.pdf

CT CSC

https://www.michigan.gov/documents/mdch/Report_104_506625_7.pdf

Mobile Routes CT

https://www.michigan.gov/documents/mdch/Report_104_506625_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2022 Review

Neonatal Intensive Care Services/Beds (NICU) Standards			
Department Recommendations: NICU Standards should continue to be regulated by CON.			
Identified Issues	Issue Recommended for Substantive Review?	Recommended Course of Action to Review Issues	Other/Comments
HFHS recommends that babies > 32 weeks, but <1,500 g that are clinically stable should be able to remain in properly staffed and equipped Special Care Nursery (SCN) rather than be transferred to level 3 NICU	No.		The requirement noted is consistent with national guidelines set by the American Academy of Pediatrics. The Department would not support any regulation that does not minimally meet national guidelines for special care nurseries.
HFHS recommends that the guideline [Sec. 12(3)(d)(i)] prohibiting mechanical ventilation via ET TUBE for more than 24 hours in a level 2 unit be increased by 24 hours for an improving patient.	No.		The requirement noted is consistent with national guidelines, and the Department would not support any regulation that does not minimally meet national guidelines for special care nurseries.
HFHS recommends that Total Parenteral Nutrition (TPN) capability be added to SCN definition for any SCN with access to pre-mixed TPN.	No.		The requirement noted is consistent with national guidelines, and the Department would not support any regulation that does not minimally meet national guidelines for special care nurseries.
Section 9 (b) – applicants now starting to lease staff from non-hospital entities/groups and counting this as no additional hospital staff needed. Add regulation to re-confirm that leasing staff must also be full time every month, 30 or 31	Yes.	The Department can draft language for the Commission to consider.	This issue was identified by the Department. This is a clarification on how the Standards are already enforced.

days, to meet the requirement of 'continuously available and on-site'.			
Other technical edits by the Department if needed.			None identified.

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the NICU Standards are scheduled for review in calendar year 2022.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 8 - 22, 2021. Testimony was received from six (6) organizations and is summarized as follows:

1. *Kenneth Berkovitz, MD, Alisha Cottrell, Ascension Michigan*
 - Supports continued regulation and recommends no changes at this time.
2. *Patrick O'Donovan, Beaumont Health*
 - Supports continued regulation and recommends no changes at this time.
3. *T. Anthony Denton, JD, MHA, University of Michigan Health System*
 - Supports continued regulation and recommends that the standards are not opened for review during this review cycle due to the proximity to the last substantive revisions which went into effect March 19, 2021.
4. *Mitchell H. DeJonge, MD, Spectrum Health*
 - Supports continued regulation and recommends that the standards are not opened for review during this review cycle due to the proximity to the last substantive revisions which went into effect March 19, 2021.
5. *Dr. Sudhakar Exhuthachan, MD, Henry Ford Health System*
 - Requests a standard advisory committee (SAC) is formed to review and revise standards to allow for the following in a Special Care Nursery (SCN):
 - i. Babies > 32 weeks, but <1,500 g that are clinically stable – Current CON standards require these babies are transferred to a level 3 NICU. HFHS feels appropriate care and be provided at a SCN that is properly staffed and equipped
 - ii. Mechanical ventilation – Current CON standards prohibit offering of mechanical ventilation via ET TUBE for more than 24 hours in a level 2 unit. HFHS requests review of guideline to increase it by 24 hours for an improving patient.
 - iii. Total Parenteral Nutrition (TPN) – Current CON standards include TPN in NICU definition. HFHS recommends that TPN capability be added to SCN definition for any SCN with access to pre-mixed TPN.

6. *Rob Casalou, Saint Joseph Mercy and Mercy Health System*

- Supports continued regulation and recommends no changes at this time.

Background:

The NICU Standards were reviewed with a SAC in 2020. The current effective date of the NICU Standards is March 19, 2021.

NICU Survey Data for 2020

Annual survey data for 2020 is the latest available and can be found here:

NICU Beds Utilization Report

https://www.michigan.gov/documents/mdch/Report_030_506175_7.pdf

Special Care Nursery Services – Transfer to NICU Utilization Report

https://www.michigan.gov/documents/mdhhs/Report_160_Special_Care_Nursery_Services_Transfer_to_NICU_736525_7.pdf

Special Care Nursery Services Utilization Report

https://www.michigan.gov/documents/mdhhs/Report_161_Special_Care_Nursery_Services_736528_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2022 Review

Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups (NH-HLTCU) Standards			
Department Recommendations: NH-HLTCU Standards should continue to be regulated by CON.			
Identified Issues	Issue Recommended for Substantive Review?	Recommended Course of Action to Review Issues	Other/Comments
COVID-19 pandemic impacted 2020 Annual Survey data, leading it to not be representative for setting future bed need. HCAM requests that 2020 Annual Survey not be used when recalculating bed need.	No.		This recommendation was provided by HCAM. NH-HLTCU bed need numbers are not due to be recalculated until 2023. At such time, the Department will determine the usefulness of 2020 Annual Survey Data.
Review Section 7(3)(c)(iii) – Practicability to track displaced residents for readmission to replacement beds.	No.		This recommendation was provided by HCAM. This section was added in 2019 for consistency with existing Project Delivery Requirements.
Review Section 7 for recognition of arrangements made through the Department of Licensing and Regulatory Affairs (LARA) Building Program Agreements, which allow for facility to temporarily close and later reopen on the current site or nearby to facilitate replacement of aging structures.	No.		Building agreements are solely under the authority of the Michigan Department of Licensing and Regulatory Affairs and cannot be used for decision making in the CON process.
Review requirements and application fees for renewal of leases.	No.		By statute, lease renewals over capital expenditure threshold are subject to CON review. The standards cannot conflict with the statute. Also, application fees are set in state statute and cannot be

			amended in the CON standards.
Review definition of “Replacement Beds” and other definitions for clarity and consistency.	Yes.	Form a workgroup and place this issue on the charge.	This issue was identified by Health Care Association of Michigan.
In the replacement (Section 7) and relocation (Section 8) language, indicate a previously approved change of ownership (CHOW) CON must be 100% complete before any replacement or relocation application can be approved.	Yes.	The Department can draft language for review and input from a Workgroup.	This issue was identified by the Department.
Review Section 6(1)(a)(iv) – previous system used by State of Michigan to publish “scope and severity grids” has been retired, report grids no longer available publicly. Consider alternative means of data collection and review.	Yes.	Form a workgroup and place this issue on the charge.	This issue was identified by the Department. LARA no longer generates the Scope/Severity grids which were used during application review.
Review multiple sections for ability to break down into subsections. For example: Section 6(1)(a)(vi) lists possible delinquent debt obligations.	Yes.	The Department can draft language for review by a workgroup or the Commission.	This issue was identified by the Department. This is a technical edit. Instead of having all 3 listed in one subsection, breaking these into 3 separate subsections will be more indicative of responses needed from applicants.
Review Section 9(3) – add language regarding QAAP, PASSAR, CMP for renewal of lease applications.	Yes.	The Department can draft language for review and input from a Workgroup.	This issue was identified by the Department.
Review Section 6 and Section 8 – addition of minimum occupancy requirement before an existing home can add new NH beds or relocate beds from another facility.	Yes.	The Department can draft language for review and input from a Workgroup.	This issue was identified by the Department.
Review addition of language to Section 11 requiring facilities remain current on taxes, fines, and fees.	Yes.	The Department can draft language for review and input from a Workgroup.	This issue was identified by the Department.
Review addition of language to Section 11(2), similar to that of	Yes.	The Department can draft language	This issue was identified by the Department.

Psych Bed Standards Section 13(2)(a) – beds operated in manner appropriate for population to be served.		for review and input from a Workgroup.	
Other technical edits by the Department if needed.			None identified.

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to “...review, and if necessary, revise each set of CON standards at least every 3 years.” In accordance with the established review schedule on the Commission Work Plan, the NH-HLTCU Standards are scheduled for review in calendar year 2022.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 8 - 22, 2021. Testimony was received from four (4) organizations and is summarized as follows:

1. *Patrick O'Donovan, Beaumont Health*
 - Supports continued regulation and recommends no changes at this time.
2. *Karen Pakkala, Spectrum Health*
 - Supports continued regulation with no changes. Recommends not reopening review of standards due to proximity to last update of review standards.
3. *Kenneth Berkovitz, MD, Alisha Cottrell, Ascension Michigan*
 - Supports continued regulation and recommends no changes at this time.
4. *Rich Farran, Health Care Association of Michigan (HCAM)*
 - Supports continued regulation of NH-HLTCU standards. Recommends the following:
 - i. Requests that 2020 Annual Survey not be used in recalculating bed need, as 2020 data is not representative for setting utilization in the future due to pandemic.
 - ii. Section 7 (3)(c)(iii) – HCAM states it is not practicable to track displaced residents. States this section may not recognize arrangements made through LARA Building Program Agreements, which allow for a facility to temporarily close and later reopen on the current site or nearby to facilitate replacement of aging structures.
 - iii. Section 9 – HCAM recommends requiring only that a waiver be filed when renewing a lease for an existing site that does not involve changes to access or quality. Also recommends that application fee be based on annual value of leased facility and not total value of multi-year lease.

- iv. Section 2 – Replacement Beds definition confusing – review and update. Review other definitions to determine if updates needed for clarity and consistency.
- v. Section 8 – Currently, both donor and receiving facilities are required to file a CON. HCAM requests a change to only require the receiving facility file CON with an addendum that includes information regarding donor facility.

Background:

The NH-HLTCU Standards were reviewed with a SAC in 2019. The current effective date of the NH-HLTCU Standards is March 19, 2021.

NH-HLTCU Survey Data for 2020

Annual survey data for 2020 is the latest available and can be found here:

Nursing Home by Age by HSA

https://www.michigan.gov/documents/mdhhs/Report_890_Nursing_Home_and_Hosp_LTCU_by_Age_by_HSA_736471_7.pdf

Nursing Home by Age by Planning Area

https://www.michigan.gov/documents/mdhhs/Report_892_Nursing_Home_and_Hosp_LTCU_by_Age_by_Planning_Area_736472_7.pdf

Nursing Home by HSA

https://www.michigan.gov/documents/mdhhs/Report_894_Nursing_Home_and_Hosp_LTCU_by_HSA_736473_7.pdf

Nursing Home by Planning Area

https://www.michigan.gov/documents/mdhhs/Report_896_Nursing_Home_and_Hosp_LTCU_by_Planning_Area_736474_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2022 Review

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units Standards

Department Recommendations: UESWL Standards should continue to be regulated by CON.

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the UESWL Standards are scheduled for review in calendar year 2022.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 8 - 22, 2021. Testimony was received from five (5) organizations and is summarized as follows:

1. *Patrick O'Donovan, Beaumont Health*
 - Supports continued regulation and recommends no changes at this time.
2. *T. Anthony Denton, University of Michigan Health System*
 - Supports continued regulation and recommends no changes at this time.
3. *Kenneth Berkovitz, MD, Alisha Cottrell, Ascension Michigan*
 - Supports continued regulation and recommends no changes at this time.
4. *Jorgen Madsen, United Medical Systems*
 - Supports continued regulation and recommends no changes at this time.
5. *Rob Casalou, Saint Joseph Mercy and Mercy Health System*
 - Supports continued regulation and recommends no changes at this time.

Background:

The UESWL Standards were reviewed by the Commission in 2019. The current effective date of the UESWL Standards is November 19, 2019.

UESWL Survey Data for 2020

Annual survey data for 2020 is the latest available and can be found here:

Litho Services – Host Site Utilization Report

https://www.michigan.gov/documents/mdch/Report_090_506618_7.pdf

Litho Services – Mobile CSC Report

https://www.michigan.gov/documents/mdch/Report_092_506619_7.pdf

Litho Mobile Routes Report

https://www.michigan.gov/documents/mdch/Report_094_506621_7.pdf

Litho Fixed Units Report

https://www.michigan.gov/documents/mdhhs/Report_096_UESWL_Fixed_Unit_736509_7.pdf